UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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CHRISTEL BILLHOFER, On Behalf of Herself and All Others Similarly Situated,

Plaintiffs,

-against-

FLAMEL TECHNOLOGIES, S.A., et al.,

Defendants.

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07 Civ. 9920

OPINION

A P P E A R A N C E S:

Attorneys for Plaintiffs

ROBBINS GELLER RUDMAN & DOWD LLP
58 South Service Road, Suite 200
Melville, NY 11747
By: Samuel H. Rudman, Esq.
David A. Rosenfeld, Esq.
Michael G. Capeci, Esq.

KESSLER TOPAZ MELTZER & CHECK, LLP
280 King of Prussia Road
Radnor, PA 19087
By: Alessandra C. Phillips
Margaret E. Onasch, Esq.

Attorneys for Defendants

HOGAN LOVELLS US LLP
875 Third Avenue
New York, NY 10022
By: Steven M. Edwards, Esq.
David Wertheimer, Esq.
Peter J. Dennin, Esq.

Sweet, D.J.

Lead Plaintiff George Jenkins ("Lead Plaintiff" or "Jenkins") has moved pursuant to Rule 15(a)(2) of the Federal Rules of Civil Procedure for leave to file the Second Amended Class Action Complaint ("SAC") alleging that the defendant Flamel Technologies, S.A. ("Flamel" or the "Defendant") and its Chief Executive Officer, Stephen H. Willard ("Willard" or the "Individual Defendant") (collectively, the "Defendants") committed securities fraud by making false and misleading statements. Based upon the conclusions set forth below, the Lead Plaintiff's motion is denied.

I. Prior Proceedings and Facts

The following facts are drawn from the First Amended Complaint ("FAC") and from the parties' affidavits and are not in dispute except as noted below.

The FAC in this putative class action was filed on March 27, 2008 and alleged securities fraud against Flamel and four of its principals. This action arose out of the March 2007 commercial launch of COREG CR, a drug developed by

GlaxoSmithKline ("GSK"), which employed Flamel's "micropump" for drug delivery.

Flamel is a French company whose common stock traded as American Depositary Receipts ("ADRs") on the NASDAQ Stock Market ("NASDAQ"). Flamel's business focuses on drug delivery technologies which allows pharmaceutical companies to develop extended release versions of their medications. Willard serves as Flamel's Chief Executive Officer. (FAC ¶¶ 4-5, 13).

Flamel partnered with GSK to develop COREG CR, a medication for heart disease and hypertension patients, which was launched in March 2007. COREG CR was intended to supplant COREG IR, another medication GSK had developed but whose patent exclusivity was expiring in September 2007, exposing it to generic competition. The primary advantage of COREG CR over COREG IR was that CR (for "controlled release") allowed for once daily dosages compared with IR (for "immediate release"), which requires twice daily dosages. (Id. ¶¶ 14-15).

The FAC alleged that COREG CR was Flamel's "lead product" whose success depended upon converting COREG IR patients to COREG CR prior to the expected entry of generic

COREG IR competition in late 2007. (Id. ¶¶ 15-16). In addition, according to the Plaintiffs, the "primary selling point" for COREG CR was that its once-daily formulation represented an "improved and better version of COREG IR" because patient compliance with their medication is a "primary issue" for cardiac patients. (Id.).

The FAC alleged that the Defendants violated Sections 10(b) and 20(a) of the 1934 Securities Exchange Act by issuing misleading public statements between March 23, 2007 through August 22, 2007 in press releases, SEC filings and quarterly earnings conference calls, which, among other things, discussed the "success" of COREG CR (Id. ¶¶ 22-27). According to the Plaintiffs, these statements were misleading because the Defendants knew, but failed to disclose, the results of the CASPER trial, which allegedly contradicted COREG CR's "primary selling point." (Id. ¶¶ 17-20).

The FAC claimed that, prior to March 23, 2007, Flamel learned the results of the CASPER trial, which showed that "switching from COREG IR to COREG CR was not associated with better drug taking compliance . . . ." (Id. ¶ 18-20). The CASPER trial results eventually became public on August 23, 2007

and the price of Flamel's ADRs "plummeted in response." (Id. ¶ 21.)

The Defendants moved to dismiss the FAC and the Honorable Charles S. Haight, Jr. denied that motion, holding that the facts pled were "more than sufficient to support an inference that Flamel knew something about the CASPER study results at some point during the 'Class Period.'" Billhofer v. Flamel Tech., SA, 663 F. Supp. 2d 288, 302 (S.D.N.Y. 2009). In addition, the Court held that Flamel's March 23 press release, which reported that COREG CR was a "success" and that "interest in [Flamel's] technologies has never been higher," was misleading because either (a) as of March 23, Flamel knew the CASPER trial results were not positive and thus knew that COREG CR was not a "success" and that GSK's "interest" in COREG CR could not be "higher" or (b) Flamel later learned the CASPER trial results but failed to update its prior statement. Id. at 298-300. The action was transferred to this Court on October 5, 2009.

On April 29, 2010, the initial plaintiff, Christel Billhofer, moved to withdraw as Lead Plaintiff and substitute Jenkins. The Defendants opposed that motion on the grounds that

document discovery obtained from non-parties demonstrated that Flamel was unaware of the CASPER trial results prior to their August 2007 publication and consequently the inference of scienter which the Court found had been raised in the FAC "can no longer be asserted in good faith." Billhofer v. Flamel Tech. SA, No. 07-9920, 2010 WL 3703838, at *3 (S.D.N.Y. Sept. 21, 2010). The substitution motion was granted, holding, among other things, that "discovery is necessary to flush out what and when Flamel knew about the CASPER trial results." Id.

The parties engaged in extensive discovery for over one year until fact discovery was completed in November 2011. On January 22, 2010, the Lead Plaintiff filed a motion to certify this action as a class action and to be certified as class representative. The Court granted that relief on March 15, 2012. On December 15, 2011, Lead Plaintiff filed his responses to the Defendants' First Requests for Admission and moved to amend the FAC.

The instant motion was heard and marked fully submitted on March 21, 2012.

II. The Proposed SAC

The SAC abandons the previous claim that the Defendants knew the CASPER trial results prior to their publication in August 2007. Instead, the SAC alleges that the Defendants may be held liable, because, despite being unaware of the CASPER results, their statements misled investors to believe that the results were positive. (SAC ¶ 2-3, 92-95). According to the Plaintiffs, discovery in this action included thousands of documents and approximately 30 depositions which revealed that the Defendants made false and misleading statements during the period of March 7, 2007 through August 22, 2007 (the "SAC Class Period").

The SAC alleges that Flamel first became aware of the CASPER trial in October 2006 when a design paper was published in the American Journal of Cardiology ("AJC") explaining its methodology and hypothesis (Id. ¶ 56). The SAC alleges that the Defendants played no part in the CASPER trials and that they were "completely unaware of the results" until August 20, 2007. (SAC ¶ 55, 64). Defendants, however, fully expected that the results of the CASPER trial would be positive and admitted that they never seriously contemplated that the results could be anything but positive. (Id. ¶ 74).

According to the Plaintiffs, without non-public information concerning the progress or results of the CASPER trial, the Defendants recklessly proceeded to issue positive statements about the "success" of COREG CR throughout the SAC Class Period. (Id. ¶¶ 97-117). In addition to making materially false and misleading statements about the success of COREG CR, the Defendants also made statements which allegedly indicated that they had access to results from GSK's clinical trial program for COREG CR. (Id. ¶¶ 100, 106). When presented with the opportunity on Flamel's earnings conference calls to disclaim knowledge of the results of the CASPER trial, the Defendants instead allowed the inference to linger that they did have access to the CASPER trial results and that those results were positive. (Id. ¶ 111).

On numerous occasions throughout the SAC Class Period, GSK expressed its concern that Flamel was both "talking up" the release of the CASPER trial results and that Flamel's public comments regarding COREG CR was extending beyond its role as manufacturer of the "micropump" technology. (Id. ¶¶ 77-91). In early May 2007, GSK's concern intensified, when it provided Flamel with a set of written guidelines to follow in composing

public statements concerning COREG CR. (Id. ¶¶ 83-84). Despite GSK's attempts to restrict Flamel's public communications concerning COREG CR, the Defendants continued to recklessly issue misleading public statements throughout the SAC Class Period. (Id. ¶¶ 97-117).

Under the SAC, the Defendants are alleged to have violated federal securities laws by issuing false and misleading statements concerning the success of COREG CR and the CASPER trial. (Id. ¶¶ 97-117).

III. The Applicable Standards

The standard governing motions to amend is a "permissive" one that is informed by a "strong preference for resolving disputes on the merits." See Williams v. Citigroup Inc., 659 F.3d 208, 212-13 (2d Cir. 2011) (citing New York v. Green, 420 F.3d 99, 104 (2d Cir. 2005)); see also Pangburn v. Culbertson, 200 F.3d 65, 70 (2d Cir. 1999) (referring to the "relaxed standard" for motions to amend). Rule 15(a) provides that leave to amend shall be "freely give[n] . . . when justice so requires." Fed. R. Civ. P. 15(a)(2).

The Supreme Court has stated that absent undue delay, bad faith, undue prejudice, or futility, the "mandate" under Fed. R. Civ. P. 15(a)(2) to freely grant leave to amend "is to be heeded." Forman v. Davis, 371 U.S. 178, 182 (1962); see also AEP Energy Servs. Gas Holding Co. v. Bank of Am. N.A., 626 F.3d 699, 725 (2d Cir. 2010 ("The rule in this Circuit has been to allow a party to amend its pleadings in the absence of a showing by the nonmovant of prejudice or bad faith.") (quoting Block v. First Blood Assocs., 988 F.2d 344, 350 (2d Cir. 1993)). For example, a motion to amend a complaint may be denied as futile when the proposed amendment "fails to state a claim or would be subject to a successful motion to dismiss." Kirk v. Heppt, 423 F. Supp. 2d 147, 149 (S.D.N.Y. 2006).

Thus, the standard for leave to amend, while permissive, is by no means "automatic." Klos v. Haskel, 835 F. Supp. 710, 715 (W.D.N.Y. 1993). The Rule 15(a) standard "is not a mechanical absolute and the circumstances and terms upon which such leave is to be 'freely given' is committed to the informed, careful judgment and discretion of the Trial Judge as he superintends the development of a cause toward its ultimate disposition." Freeman v. Continental Gin Co., 381 F.2d 459, 468 (5th Cir. 1967).

For example, under Rule 15(a), amendment is appropriate when discovery reveals facts that contradict those in the operative complaint. See Quattrone v. Erie 2 Chautauqua-Cattaraugus Bd. of Co-op. Educ. Services, No. 08-367(JTC), 2011 WL 294496, at **2, 9 (W.D.N.Y. Jan. 27, 2011) (granting leave to amend the complaint to conform the pleadings to evidence obtained in discovery); Mellon Bank v. Alexander Wescott & Co., No. 98-2650(AGS), 1999 WL 504914, at *5 (S.D.N.Y. July 16, 1999) (noting that "[i]t is not inappropriate to permit an amendment to pleadings in order to conform the pleadings to the evidence unearthed by discovery"); Matarazzo v. Friendly Ice Cream Corp., 70 F.R.D. 556, 559 (E.D.N.Y. 1976) (stating that "discovery often justifies a subsequent amendment to the complaint.").

To plead a claim for violation of Section 10(b) and Rule 10b-5 thereunder, "a complaint must allege that a defendant '(1) made misstatements or omissions of material fact; (2) with scienter; (3) in connection with the purchase or sale of securities; (4) upon which plaintiffs relied; and (5) that plaintiffs' reliance was the proximate cause of their injury.'" In re Citigroup Inc. Sec. Litig., 753 F. Supp. 2d 206, 232 (S.D.N.Y. 2010) (quoting In re IBM Corp. Sec. Litig., 163 F.3d

102, 106 (2d Cir. 1998)); See also Janus Capital Group, Inc. v. First Derivative Traders, --- U.S. --, 131 S. Ct. 2296, 2301 n.3, 180 L. Ed. 2d 166 (2011); Slayton v. Am. Express Co., 604 F.3d 758, 765 (2d Cir. 2010).[1] An omission is actionable only if the Defendants were "subject to a duty to disclose the omitted facts." Vladimir v. Bioenvision Inc., 606 F. Supp. 2d 473, 484 (S.D.N.Y. 2009). As the Supreme Court has held, "[s]ilence, absent a duty to disclose, is not misleading." Basic Inc. v. Levinson, 485 U.S. 224, 239 n.17, 108 S. Ct. 978, 99 L. Ed. 2d 194 (1988).

The proposed pleading must meet the requirements of Rule 8(a) of the Federal Rules of Civil Procedure by asserting "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007). It is not sufficient if the facts alleged show only "a sheer possibility that a defendant has acted unlawfully." Ashcroft v. Iqbal, 556 U.S. 662, 129 S. Ct. 1937, 1949, 173 L. Ed. 2d 868 (2009). Rather, a

[1] Significantly, the Defendants concede that Lead Plaintiff has adequately alleged the "in connection with," reliance and causation elements. Defendants also do not challenge the materiality of the alleged false and misleading statements. Instead, Defendants argue that the statements identified by Lead Plaintiff are not false or misleading, and that Lead Plaintiff has failed to adequately allege scienter. (See Def. Memo. at 11).

"claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. In other words, plaintiff must allege facts sufficient to "nudge[ ] their claims across the line from conceivable to plausible." Twombly, 550 U.S. at 570.

The proposed amendment must also satisfy the heightened pleading standards of Rule 9(b) of the Federal Rules of Civil Procedure and the Private Securities Litigation Reform Act, 15 U.S.C. § 78u-4(b) (the "PSLRA"). See, e.g., Slayton, 604 F.3d at 766. The PSLRA "d[id] not change the standard of review for a motion to dismiss." In re Initial Pub. Offering Sec. Litig., 241 F. Supp. 2d 281, 332 (S.D.N.Y. 2003) ("IPO I"). "[T]he heightened pleading standard under the [PSLRA] . . . applies only to the element of scienter; all other elements of a § 10(b) claim are governed by traditional pleading standards under Fed. R. Civ. P. 8(a) or 9(b)." Freudenberg v. E*Trade Fin. Corp., 712 F. Supp. 2d 171, 179 (S.D.N.Y. 2010).

Thus, the heightened pleading standards of the PSLRA and Rule 9(b) must be applied in assessing scienter. See Katz v. Image Innovations Holdings, Inc., 542 F. Supp. 2d 269, 272

(S.D.N.Y. 2008). To plead scienter, a plaintiff must plead "with particularity" the "facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2); Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 314, 127 S. Ct. 2499, 168 L. Ed. 2d 179 (2007). These facts must demonstrate a "mental state embracing intent to deceive, manipulate, or defraud," which often may be shown by proof of "conscious recklessness." South Cherry St., LLC v. Hennessee Group LLC, 573 F.3d 98, 108-09 (2d Cir. 2009). In Tellabs, the Supreme Court explained that a "strong inference" of scienter "must be more than merely plausible or reasonable" but instead must be "cogent and compelling," an assessment that requires a court to "consider plausible, nonculpable explanations for the defendant's conduct." Tellabs, 551 U.S. at 314, 324.

The Defendants have contended that the motion for amendment is futile challenging the proposed pleading for failing to state a claim. See A.V. by Versace, Inc. v. Gianni Versace S.p.A., 87 F. Supp. 2d 281, 298 (S.D.N.Y. 2000) (noting that a proposed amendment challenged on the ground of futility will be assessed to see if the amendment states a claim for relief); see also Ballard, 2008 WL 4298572, at *3 (stating that

"[a] proposed amendment to a pleading would be futile if it could not withstand a motion to dismiss pursuant to Rule 12(b)(6).").

According to the Second Circuit, the complaint "must (1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." ATSI Commc'ns., Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 99 (2d Cir. 2007). The plaintiff must identify each allegedly misleading statement and "'state with particularity the specific facts in support of [plaintiffs'] belief that [defendants'] statements were false when made.'" 15 U.S.C. § 78u-4(b)(1); Rombach v. Chang, 355 F.3d 164, 172 (2d Cir. 2004). However, a plaintiff is still not required to plead "detailed evidentiary matter." In re Scholastic Corp. Sec. Litig., 252 F.3d 63, 72 (2d Cir. 2001).

"[F]or the purposes of evaluating futility, the 12(b)(6) standards is applied: all well pleaded allegations are accepted as true, and all inferences are drawn in favor of the pleader." E*Trade Fin. Corp. v. Deutsche Bank AG, 420 F. Supp. 2d 273, 282 (S.D.N.Y. 2006); see also IPO I, 241 F. Supp. 2d at

331 (holding that a court must accept the complaint's allegations as true and construe all reasonable inferences in the plaintiff's favor).

IV. The Allegations Of False And Misleading Statements Are Inadequate

The Partnership Allegations

Rule 10b-5(b) makes it unlawful for a person "to make any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b-5. "[O]nce corporate officers undertake to make statements, they are obligated to speak truthfully and to make such additional disclosures as are necessary to avoid rendering the statements made misleading." Freudenberg, 712 F. Supp. 2d at 180-81; see also In re Marsh & McLennan Cos. Secs. Litig., 501 F. Supp. 2d 452, 469 (S.D.N.Y. 2006) ("When a corporation . . . make[s] a disclosure - whether it be voluntary or required - there is a duty to make it complete and accurate.")

Although Rule 10b-5 does not create an affirmative duty to disclose all material nonpublic information in a company's possession, "the lack of an independent duty to speak in the first instance becomes irrelevant once a party chooses to discuss material issues, because upon choosing to speak one has a duty to be both accurate and complete." Lapin v. Goldman Sachs Group, Inc., 506 F. Supp. 2d 221, 237 (S.D.N.Y. 2006). Indeed, "statements, although literally accurate, can become, through their context and manner of presentation, devices which mislead investors." In re Sanofi-Aventis Secs. Litig., 774 F. Supp. 2d 549, 561 (S.D.N.Y. 2011). As a result, "if a reasonable investor would so regard the omitted fact [as material], it is difficult to imagine a circumstance where the prior statement would not be rendered misleading in the absence of disclosure." Id. at 564 (quoting In re Time Warner Inc. Secs. Litig., 9 F.3d 259, 267-68 (2d Cir. 1993)).

The SAC has alleged that the Defendants led investors to believe they knew the results of the CASPER trial because Flamel characterized its relationship with GSK as a "partnership" and Willard, in an August 2, 2007 investor conference call, said that GSK "share with us information." (SAC ¶¶ 95, 116; Wertheimer Decl. Ex. 7 at 18.)

In its public disclosures until 2007, Flamel referenced its relationship with and GSK as partners, collaborative partners, and in a partnership regarding COREG CR. For example, in Flamel's 2005 and 2006 Form 20-F disclosures, Flamel stated that "[w]e currently have [a] collaborative agreement[ ] with GlaxoSmith Kline." The disclosures used the terms "partners," "collaborative agreements" and "partner agreements" in describing the relationship between Flamel and GSK.

Willard used Flamel's quarterly conference calls as a further opportunity to describe Flamel and GSK's relationship as that of a partnership in regards to COREG CR. For instance, on Flamel's March 8, 2007 conference call, in the course of extensively quoting senior GSK executives' views on COREG CR's prospects, Willard stated that "[o]ur partner, GSK, continues to say that [COREG CR] will launch this quarter" and "it is not our place to get out in front of our partner, GlaxoSmithKline[.]" Willard followed these statements by proclaiming that "[o]ur clinical trial programs, both for ourselves and our partners, are moving forward well and we expect results later this year." (SAC ¶ 100). According to the Lead Plaintiff, Willard did not disclose that, even though Flamel and GSK were "partners" on COREG CR, GSK

did not share proprietary information with Flamel, including the results of COREG CR clinical trials.

Similarly, on Flamel's May 7, 2007 conference call, Willard stated that "Glaxo is a very good partner" and "we do have a very special relationship with Glaxo," and commented on GSK's plans for releasing clinical trial information, with specific mention of the CASPER trial. (SAC ¶¶ 111-12). Again, Willard did not disclose that Flamel was denied access to COREG CR clinical trial results.

On Flamel's August 2, 2007 conference call, Willard repeated that "Glaxo is a good partner" and added that "[w]e do have a good relationship with GSK. We always have had. We are very important to them because of our manufacturing role with them. They share with us information . . ." (SAC ¶ 116). When presented with a question concerning the public release of information about COREG CR clinical trials, specifically the CASPER trial, Willard responded that "[it's] for GSK to be able to tell people about."

The term "partnership" is simply too broad and vague to support the inference the SAC seeks to impose. See, e.g.,

San Leandro Emergency Med. Group Profit Sharing Plan v. Philip Morris Cos., 75 F.3d 801, 810-11 (2d Cir. 1996) (finding that vague reference to marketing plan does not support inference of specific representation about a particular marketing strategy). In addition, that inference is less reasonable given the Defendants' disclosures, which described the limited scope of the Flamel and GSK "partnership" and which portrayed Flamel as a vender to GSK, not a full-fledged partner with access to all of GSK's corporate secrets.

For example, statements limiting GSK's and Flamel's relationship were also made at various conferences. See also Flamel Nov. 2, 2006 Conf. at 22 ("[W]e really don't have much control over what Glaxo does" and "[t]hey definitely do things a little differently than we would do if we were calling the shots"); Flamel May 7, 2007 Conf. at 18 ("I don't ever want to have a sales force;" "[w]e outsource the sales of the product" to GSK); Id. at 21 ("[I]t's probably fair to say that all of the players involved in COREG CR, probably, you know, Glaxo has the most information to try to make predictions about how this product is going to go. They control a lot of the resources."); Flamel Aug. 2, 2007 Conf. at 18 ("Flamel manufactures COREG CR

particles;" "GSK controls COREC CR sales force") (Wertheimer Decl. Ex. 2, 5, 7-8).

Flamel's 2005 and 2006 Form 20-F disclosures, which were filed before and during the proposed Class Period, also disclosed:

> We market and sell our technologies to third parties, who incorporate our technologies into their products. We depend upon collaborative agreements with pharmaceutical and biotechnology companies to develop, test, obtain regulatory approval for and commercialize products that incorporate our drug delivery technologies;
>
> and
>
> Under our partner agreements, our pharmaceutical company partners typically assume responsibility for all clinical regulatory and marketing costs.

Willard similarly stated in his quarterly conference calls with investors that "our job was to deliver the formation, help with the [FDA] approval and ensure the supply. And everything else is really for Glaxo."

Accordingly, the statements above do not establish that the Defendants intended to inaccurately convey their relationship with GSK.

The Clinical Trials and Subsequent Allegations Are Insufficient

On Flamel's March 8, 2007 conference call, Willard stated that "[o]ur clinical trial programs, both for ourselves and our partners, are moving forward well and we expect results later this year." (SAC ¶ 100). According to the SAC, this statement created misleading inferences that Defendants had access to the results of GSK's clinical trials for COREG CR, including the CASPER trial, and that those clinical trials were "moving forward well." (SAC ¶ 101). According to the Lead Plaintiff, the Defendants' failure to qualify this statement by speaking accurately and completely, explaining that they did not have access to non-public information concerning GSK's clinical trial programs for COREG CR and that they had no basis for assessing that these programs were "moving forward well" - rendered Willard's March 8, 2007 statements materially misleading. (Memo in Support at 17-18.)

In the March 8 conference call, however, Willard made no reference to the CASPER trial. Willard did refer to several GSK-sponsored clinical trials involving COREG CR reported on the website clinicaltrials.gov concerning combination products to address hypertension. (Flamel Mar. 8, 2007 Conf. at 2, 10-11

(Wertheimer Ex. 2)). He mentioned clinical trials that Flamel itself had undertaken for medications employing Flamel's Medusa technology, which was unrelated to the Micropump technology used to create COREG CR (SAC ¶¶ 24, 31). The word CASPER, however, does not appear in the conference transcript nor is there any reference to a compliance trial involving COREG CR. The assumption that a reasonable investor would assume that he was talking about the CASPER trial is implausible. See San Leandro, 75 F.3d at 810-11 ("reasonable investor" would not conclude that company's generalized statement about its marketing plans "committed" the company to a "particular marketing strategy" or "foreclosed all alternatives"). Accordingly, Willard's silence about the CASPER trial cannot be misleading as a matter of law. Basic Inc., 485 U.S. at 239 n.17.

The phrase "moving forward well" conveys no meaningful, objective data that an investor would rely upon. It is simply an assertion that courts have found to be immaterial. See, e.g., In re GPC Biotech AG Sec. Litig., No. 07-06728(DC), 2009 WL 5125130, at *4-5 (S.D.N.Y. Dec. 29, 2009) (statements conveying allegedly misleading impression that clinical "trial was going well" are immaterial puffery); Pollio v. MF Global,

608 F. Supp.2d 564, 571 (S.D.N.Y. 2009) (statement that "the franchise is performing well" is merely optimistic puffery).

Willard's statement also rebuts the inference the Plaintiff seeks to draw when he said "we expect results later this year." Such a statement suggests that the Defendants did not currently know the trial results. Moreover, Willard's statement is protected as a non-actionable opinion. Because no reasonable investor could conclude from Willard's statement that he knew about the CASPER trial results and that the results were positive, the allegation is implausible. See In re Aegon N.V. Secs. Litig., No. 03-0603, 2004 WL 1415973, at *5 (S.D.N.Y. June 23, 2004) ("The truth of factual allegations that are contradictions by documents properly considered on a motion to dismiss need not be accepted."); cf. Gissin v. Endres, 739 F. Supp. 2d 488, 509-11 (S.D.N.Y. 2010) (rejecting fraud claim because "[w]hen the statements at issue are read together with the cautionary language, there is no plausible indication that a reasonable investor could have been misled . . . .").

In the March 23, 2007 press release announcing the United States release of COREG CR, Willard stated:

> COREG CR is the first marketed product incorporating Flamel's Micropump technology. The success of the COREG CR program has generated considerable interest in our Micropump technology as well as in our Medusa technology platform for the delivery of protein and peptides. Interest in both technologies has never been higher.

(SAC ¶ 102). In addition, in Flamel's May 7, 2007 press release announcing first quarter 2007 financial results, Willard is quoted as saying "[w]e are pleased with the early success of the COREG CR launch." (SAC ¶ 106). Finally, in Flamel's August 1, 2007 press release announcing second quarter 2007 financial results, Willard is quoted as saying "[r]egarding COREG CR, we believe it has strong ongoing potential in all indications." (SAC ¶ 112).

That the Defendants could believe COREG CR was a "success" without knowing the CASPER trial results appears to be the basis for Judge Haight's holding that the Defendants' March 23 statement did not imply that they knew the CASPER results. The Court held that the March 23 statement could not be misleading because it inferred the opposite conclusion about the Defendants' knowledge, that they were "not in possession of material information - such as a negative outcome in the CASPER study - that would detract from the 'success' of COREG CR." Billhofer, 663 F. Supp. 2d at 298. Now that Plaintiff has

conceded that the Defendants did not know the CASPER trial results, the Court's inference as to the March 23 statement is consistent with the Defendants' knowledge, or more aptly, lack of knowledge. Accordingly, the March 23 statement, as well as the May 7 and August 1 statements, cannot be held to be misleading.

In addition, the term "success" is simply too broad and generalized a statement to permit a plausible inference that the Defendants were specifically representing that they knew the CASPER trial results, especially given that, as reported by the Flamel securities analysts, GSK was sponsoring numerous clinical trials involving COREG CR in addition to the CASPER trial. See, e.g., Punk Zielgel & Co. ("PZC"), Mar. 9, 2007 Report at 4-5 (listing seven of GSK's COREG CR clinical trials, including the CASPER trial) (Wertheimer Decl. Ex. 20). Broad statements about a company's business to plead an actionable omission concerning a specific topic - had been rejected. See, e.g., San Leandro, (vague statement about company's plans "cannot have led any reasonable investor to conclude that [company] had committed itself to a particular marketing strategy and had foreclosed all alternatives.").

In addition, the Defendants' "success" statements constituted expressions of "corporate optimism" or opinions that the Plaintiff has failed to allege were either false or not honestly believed. As the Second Circuit has held, the hallmark of an opinion is that it does not express "matters of objective fact" which can be assessed against an "objective standard" but instead conveys a belief or "judgment" whose "determination is inherently subjective." Fait v. Regions Fin. Corp., 655 F.3d 105, 110-13 (2d Cir. 2011).

Because the Defendants' statements are opinion, they can be found misleading only if the Plaintiff alleges facts sufficient to show "that defendant's opinions were both false and not honestly believed when they were made." Id. at 113. See also Sanofi-Aventis, 774 F. Supp. 2d at 567 (to plead an opinion as misleading, plaintiff must allege "with particularity" "provable facts" to demonstrate that the statement of opinion is both objectively and subjectively false") (collecting cases). Courts have held that recklessness will not suffice to plead a misleading opinion but instead required that plaintiff "allege that the defendant did not actually believe the stated opinion." In re Bank of Am. Corp.

Sec., Deriv., & ERISA Litig., 757 F. Supp. 2d 260, 310 & n.12 (collecting cases).

The Plaintiff maintains that the March 23, 2007 statement is misleading because it falsely implied that GSK's "interest" in COREG CR had never been higher. (SAC ¶¶ 103-04). No facts, however, are pled to show that the opinion was "both false and not honestly believed" when made. Fait, 655 F.3d at 113.

With respect to falsity, Plaintiff's claim relies solely on an inference that because GSK knew the results of the CASPER trial, even though Flamel did not, "it is reasonable to conclude" that GSK's interest was not "higher." (SAC ¶ 103). However, to satisfy Rule 9(b), Plaintiff must plead "specific facts" to support his claim of falsity. Rombach, 355 F.3d at 172. Although the Lead Plaintiff has now taken extensive discovery of GSK, including obtaining tens of thousands of pages of documents and deposing six GSK witnesses, the SAC has not pled any support from any document, email or witness testimony for the assertion that GSK lost interest in COREG CR due to its knowledge of the CASPER trial results.

Regardless of GSK's actual "interest" in COREG CR, the SAC has failed to plead facts supporting a "strong inference" that the Defendants did not honestly believe, or even were reckless in believing, that GSK's interest in COREG CR had "never been higher" and that COREG CR was a "success." As the Plaintiff concedes, despite Willard having inquired about them, GSK never informed the Defendants about the CASPER trial results prior to late August 2007, and Willard honestly believed the CASPER trial would show positive results. No evidentiary source is cited to show that the Defendants knew of GSK's supposed lack of interest or otherwise did not honestly hold the opinions they stated.

Moreover, the facts pled and those that could be considered on a motion to dismiss present a "compelling" case that the Defendants believed that GSK's interest in COREG CR was never "higher" and that CORER CR was a success. These include:

- In January and February 2007 investor conference calls and presentations, GSK predicted that it would convert more than 50% of COREG IR patients to COREG CR, a conversion that Plaintiff contends was critical to the "success" of COREG CR (SAC ¶ 47);

- In a January 2007 investor presentation, GSK predicted that it would have no "difficulty at all getting [COREG CR] into the formularies," GSK Jan. 4, 2007 Conf. at 4 (Wertheimer Decl. Ex. 11), a result which

directly impacted COREG CR's success because, Plaintiff asserts, formulary placement was a "key factor" in converting patients to COREG CR (Id. ¶ 48);

- In a February 2007 investor conference call, GSK predicted that COREG CR could be marketed beyond COREG IR's congestive heart failure patient base to reach the much larger market of patients suffering from hypertension; GSK Feb. 8, 2007 Conf. at 19 (Wertheimer Decl. Ex. 12);

- In mid-2006, SK, due to its anticipated demand for COREG CR, agreed to fund Flamel's expansion of its COREG CR manufacturing factory to increase output by 50%, Flamel 2006 Form 20-F, filed with the SEC on May 30, 2007 ("2006 20-F") at 20, 30-31; RFA Answers No. 139 (Wertheimer Decl. Exs. 10, 26);

- Throughout March to August 2007, Flamel, as a result of GSK's existing demand for COREG CR microparticles, operated its manufacturing factory on a 24 hour/7 days per week schedule, Flamel 2006 20-F at 30; RFA Answers No. 136 (Wertheimer Decl. Exs. 10, 26);

- By March 2007 (and continuing through August 2007), GSK, as a result of its anticipated demand for COREG CR, discussed with Flamel plans to expand Flamel's manufacturing facility to increase output by 100%, Flamel May 7, 2007 Conf. at 8; RFA Answers No. 140 (Wertheimer Decl. Exs. 5, 26).

Willard discussed most of these facts in his March 8, 2007 conference call with investors as the basis for his belief in the success of COREG CR, Flamel Mar. 8, 2007 Conf. at 2, 8-12 (Wertheimer Decl. Ex. 2). Securities analysts following Flamel observed these same factors and concluded, like Willard, that they reflected GSK's strong interest in COREG CR and pointed to

COREG CR being a success. See, e.g., Merriman Curhan Ford ("MCF") Jan. 9, 2007 Report at 1-2; MCF Mar. 9, 2007 Report at 1-2; PZC Mar. 9, 2007 Report at 1-3 (Wertheimer Decl. Exs. 18-20).

With respect to the Defendants' May 7, statement that they "are pleased with the early success of the COREG CR launch," the SACAS has alleged that it was misleading because it "implied that both Flamel and GSK deemed the launch of COREG CR to be an early success" whereas "Flamel had no knowledge as to GSK's assessment of the COREG CR launch." (SAC ¶ 107). Even assuming an investor might have understood Willard to be referring to both Flamel and GSK in his opinion, an expansive interpretation of the word "we," the SAC has not alleged facts to show that GSK was not pleased by the "early success" of the COREG CR launch.

No facts are pled to show that Willard did not honestly believe his opinion. During GSK's quarterly earnings conference call on April 25, 2007, almost two weeks before Flamel's May 7 press release, GSK represented that "[w]e are on track in terms of" the COREG CR launch and further stated:

> [O]ur third biggest opportunity is COREG CR, where sales detailing began at the end of March. We believe cardiologists wanted a once-a-day COREG, and so far, we're very encouraged by the early prescriptions. Now, it's early, but just after three weeks, more than one out of ten new scrips for Coreg are beings written for Coreg CR by cardiologists. And this is a great first step, because we know that cardiologists will lead, and the primary care physicians will follow.

Slides presented by GSK during that same call also proclaimed "Coreg CR off to a strong start." These statements by GSK establish a "compelling" case that the Defendants' honestly believed their May 7 Opinion.

With respect to Flamel's August 1 Opinion that "we believe [COREG CR] has strong ongoing potential in all indications," the SAC does not contend that their statement implicated GSK's interest in COREG CR. (SAC ¶ 113). The prior week, during its July 25, 2007 quarterly earnings conference, GSK discussed its strong commitment to the COREG CR marketing effort, including its assignment of 2,000 sales representatives to promote the product and its disclosure that "two of the big three commercial" formularies for managed care had "now moved COREG CR into a tier 2 coverage," facts that Willard emphasized in his August 2, 2007 conference call as a basis for his belief in COREG CR's "strong ongoing potential."

The SAC has alleged that the Defendants led investors to believe they knew the CASPER trial results because of two statements they made in the March 7 and May 7, 2007 press releases, which asserted that reduced medication dosing provides patients a convenience benefit and leads to improved patient compliance. (SAC ¶¶ 98, 106; Wertheimer Decl. Exs. 1, 4.)

It is "obvious" that a securities law action "may not rely upon statements that are true." In re Nokia Oyj (Nokia Corp.) Sec. Litig., 423 F. Supp. 2d 364, 393 (S.D.N.Y. 2006). Both of the challenged statements have been established to be true. The March press release, which discusses Flamel's two drug delivery platforms, asserts that there are "obvious benefits associated with more convenient dosing regimens." (SAC ¶ 98). The SAC has pled no facts to suggest that statement was false. Indeed, the statement is essentially tautological, "more convenient dosing regimens" have "obvious benefits."

The statement contained in the May 7 press release stated that "[i]t is well established that once-daily medications lead to greater patient compliance." (SAC ¶ 106). No facts have been alleged to dispute that statement. The clinical paper describing the CASPER trial methodology,

published in an October 2006 supplement to the AJC, explained that the CASPER trial was premised on prior clinical trials which showed that reduced drug dosing leads to increased compliance. (SAC ¶¶ 50-51). Indeed, the Lead Plaintiff has admitted that prior clinical trials "had shown that reducing patients' medication dosing leads to improved compliance with patients' medication regimes." (See RFA Answers No. 125 (Wertheimer Decl. Ex. 26)).

Because the Defendants accurately described prior clinical findings, they were not obligated to speculate on the results of unpublished clinical trials, such as CASPER, about which they did not know. As courts have consistently held, accurate statements of "historical facts" are "not actionable under the securities law." See, e.g., In re IAC/InterActiveCorp Secs. Litig., 478 F. Supp. 2d 574, 594 (S.D.N.Y. 2007).

Neither the March 7 nor May 7 statement made any reference to the CASPER trial. Accordingly, the Defendants' "silence" with respect to the CASPER trial cannot be misleading. Basic Inc., 485 U.S. at 239 n.17.

Moreover, on the same day as the May 7 press release, Willard stated in an investor conference call that he did not know when GSK would be releasing the CASPER trial results and emphasized that it would be "within GSK's call as to how that data comes out." (SAC ¶ 110). Given Willard's comments, no reasonable investor would have construed Flamel's May 7 press release to be a disclosure by Flamel that the CASPER trial had shown positive results.

Even if some investors, upon reading the March 7 and May 7 press releases, might have assumed that CASPER would show, consistent with past clinical trials, that COREG CR increased patient compliance rates, they would not have been alone. The CASPER researchers made the same assumption (SAC ¶ 53), as did many of the scientists who published research articles in the 2006 AJC and stock analysts who covered Flamel. Indeed, if the Defendants had said in the March 7 or May 7, 2007 press releases that they believed the CASPER trial would show improved compliance, that prediction, although ultimately proven incorrect, would not have been actionable because (a) the Defendants honestly held that opinion (SAC ¶¶ 73-74); (b) there was ample grounds, as discussed above, to support the reasonableness of the opinion; and (c) the Defendants were

unaware of any facts contradicting the opinion (SAC ¶ 64). See Fait, 655 F.3d at 113 (opinions actionable only if "not honestly believed when they were made."). To hold the Defendants responsible for assumptions investors might have made on their own after reading the Defendants' statements is improper. U.S. v. Finnerty, 533 F.3d 143, 150 (2d Cir. 2008) (defendant not liable for assumptions independently made by investors).

Accordingly, neither the clinical trials nor the statements, or lack thereof, made subsequently to the trials indicate that the Defendants misled investors.

Plaintiff Fails to Plead Facts Demonstrating Scienter

Scienter can be "established by alleging facts to show either (1) that Defendants had the motive and opportunity to commit fraud, or (2) strong circumstantial evidence of conscious misbehavior or recklessness." ECA & Local 134 IBEW Joint Pension Trust v. JP Morgan Chase Co., 553 F.3d 187, 198 (2d Cir. 2009).

Judge Haight previously found that Plaintiff had failed to plead motive because the FAC contained no allegation

that Willard or any other Flamel executives sold any shares of Flamel stock or otherwise received any personal benefit from the alleged fraud. Billhofer, 663 F. Supp. 2d at 301. As proposed, the SAC has not supplied those missing factual allegations.

Because the SAC fails to plead that the Defendants had any "compelling motive to mislead investors . . . a number of competing inferences regarding scienter arise." Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital Inc., 531 F.3d 190, 197 (2d Cir. 2008). To state a Section 10(b) claim, the inferences raised by Plaintiff's factual allegations must do more than suggest that the Defendants "could" have acted recklessly. South Cherry Street, 573 F.3d at 110. Even under Rule 8(a), facts suggesting only that it was "conceivable" for the Defendants to have engaged in unlawful conduct are not sufficient. The PSLRA's heightened pleading standard demands that the facts pled support an inference of recklessness that it "cogent and compelling," particularly in light of any non-culpable explanations for the Defendants' conduct. Tellabs, 551 U.S. at 314, 324. Indeed, the "strength of the circumstantial allegations must be correspondingly grater" because plaintiff has not pled any motive to commit fraud. ECA, 553 F.3d at 198-99. Cf. In re PXRE Group, Ltd. Sec. Litig., 600 F. Supp. 2d

510, n.21 (S.D.N.Y. 2009) (plaintiff's failure to plead motive "certainly makes competing, non-fraudulent inferences more 'compelling' for purposes of the Tellabs analysis"), aff'd, 357 Fed. Appx. 393 (2d Cir. 2009).

"Conscious" recklessness, as required under Section 10(b), is defined as "an extreme departure from the standards of ordinary care . . . to the extent that the danger was "either known to the defendant or so obvious that the defendant must have been aware of it." ECA, 553 F.3d at 198 (internal citations omitted). In this case, it was far from "obvious" to the Defendants, and certainly not "known" by them, that their statements could be misconstrued to suggest that they knew the CASPER trial results. Indeed, for the reasons discussed above, the Defendants' statements were not misleading because they do not say anything about the Defendants' knowledge of the CASPER trial results.

In similar non-disclosure cases where the duty to disclose was "not so clear," courts have consistently held that an alleged omission alone does not plead recklessness. Kalnit v. Eicher, 264 F.3d 131, 143 (2d Cir. 2001). Indeed, were the rule otherwise, "an honest but negligent mistake in judging how

much detail needs to be included in public statements" might suffice to state a securities fraud claim, which would be contrary to the explicit terms and purpose of Section 10(b), "to punish knowing fraud or reckless behavior, not mistakes that arise from negligent or even grossly negligent behavior." In re GeoPharma, Inc. Secs. Litig., 411 F. Supp. 2d 434, 437 (S.D.N.Y. 2006).

The SAC has alleged that Willard acted recklessly because he believed it "was highly improbable" that the CASPER trial would show negative results. (SAC ¶¶ 73, 93). Willard's optimism over the CASPER trial outcome does not explain why he would mislead investors about the CASPER trial. If corporate optimism alone could serve as a basis to infer scienter, "virtually every company in the United States that experiences a downturn in stock price could be forced to defend securities fraud actions." Kalnit, 264 F.3d at 140.

The Lead Plaintiff has contended, based on Judge Haight's opinion, that Willard allowed investors to believe he knew the CASPER trial results by declining to answer, during Flamel's May 7 and August 2, 2007 conference calls, analysts' questions concerning when the CASPER trial results would be

published. (Memo. in Support at 4 & n. 3.) Quoting Judge Haight, the Plaintiff contends that by remaining silent, Willard allowed "the inference to linger in the air that Flamel knew the results of these studies, even if it was "within GSK's call" to decide when to release those results." (Id. at 4 n.3 (quoting Billhofer, 663 F. Supp.2d at 304)).

In his opinion, however, Judge Haight was not addressing the scienter issue raised by the Plaintiff's new theory as to whether Willard acted recklessly by remaining silent. Rather, Judge Haight was addressing the entirely different issue of whether, given Willard's alleged knowledge of the CASPER trial results, Willard's silence suggested that he acted recklessly when making his March 23, 2007 statements concerning the "success" of COREG CR.

The dispositive analysis from Judge Haight's opinion, which Plaintiff ignores, is that, absent knowledge of the CASPER trial results, Willard's "silence would be more than acceptable." Billhofer, 663 F. Supp. 2d at 303; see also Basic Inc., 485 U.S. at 239 n.17 (silence "is not misleading"). Given that conclusion, it follows that Willard cannot have acted recklessly by remaining silent. San Leandro, 75 F.3d at 813

(because plaintiff failed to allege any false statements, he "obviously fails to allege facts constituting circumstantial evidence of reckless or conscious misbehavior" by defendants).

The proposed pleading also cites several internal GSK emails and notes in which GSK employees supposedly expressed "concern" over various Flamel communications, including draft and final press releases and private emails to third parties discussing COREG CR. (See SAC ¶¶ 79-91). However, none of the GSK documents address the Defendants' statements at issue and none suggest that GSK believed that the Defendants had made a false or misleading statement about the CASPER trial or that GSK communicated such a belief to the Defendants.

The "concern" raised in the GSK documents related generally to any Flamel statement about COREG CR, not to the CASPER trial specifically. The GSK documents suggest that GSK wanted Flamel to say nothing about COREG CR, apart from discussing its drug delivery technology and manufacturing capabilities. (Id. ¶ 83). That preference is not surprising given that, as is conceded, GSK failed to disclose to Flamel the results of the CASPER trial until at least August 20, 2007, even

though GSK knew the results long before the March 2007 launch of COREG CR. (Id. ¶¶ 59-61, 64).

Two internal GSK emails have been cited, that were communications not shared with Flamel, in which GSK employees complained that Flamel had discussed a "new clinical trial for COREG CR" with a Deutsche Bank analyst and posted a "PowerPoint presentation" to Flamel's website. (Id. ¶¶ 81, 5). Several GSK internal emails have been cited which discuss GSK's desire for Flamel to avoid making any public comparisons of COREG CR and COREG IR and nothing that GSK had "deleted" such comparisons from draft Flamel statements that GSK had reviewed. (Id. ¶¶ 82-84).

None of the emails suggests that the statements Flamel had made, or drafted, were inaccurate or unsupported. More importantly, none of them addresses the statements challenged in the proposed pleading or suggest that the Defendants had said anything misleading about the CASPER trial.

The four remaining documents that the SAC cited that actually mention the CASPER trial provide no support for a fraud claim. Taken together, the GSK documents have no bearing on the

Defendants' statements at issue, they do not raise a "strong inference" of scienter.

As discussed above, the Plaintiff has failed to pled facts that raise a "strong inference" of scienter by the Defendants sufficient to plead a § 10(b) claim. Accordingly, the Lead Plaintiff's motion is futile because it "fails to state a claim or would be subject to a successful motion to dismiss." Kirk, 423 F. Supp. 2d at 149.

V. Conclusion

Based upon the conclusions set forth above, the motion of the Lead Plaintiff for leave to file the SAC is denied.

It is so ordered.

New York, NY
July 25, 2012

ROBERT W. SWEET
U.S.D.J.